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09/29/2010

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NOBUSHIGI DOISAKI, TSUYOSHI KORIYAMA,
JUN OKANO, and SHUJI JINNO,
Appellants¹

Appeal 2010-001942
Application 10/535,413
Technology Center 1600

Before CAROL A. SPIEGEL, DONALD E. ADAMS, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL²

¹ The real party in interest is NIPPON SUISAN KAISHA, LTD. (Brief on Appeal filed 8 July 2008 ("App. Br.") at 2 (supplemented 25 July 2008)). This decision also cites the Examiner's Answer mailed 11 December 2008 ("Ans."), the Communication mailed 11 August 2009 ("Communication"), the Reply Brief for Appellants filed 22 January 2009 ("Reply Br."), and the Specification ("Spec.") of Application 10/285,810 ("the 810 Application").

² The two-month period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

Appellants appeal under 35 U.S.C. § 134(a) from an Examiner's final rejection of claims 1 and 5-20 (App. Br. 2; Ans. 2). Claim 4, the only other pending claim, is withdrawn from consideration (Advisory Action mailed June 19, 2008). We have jurisdiction under 35 U.S.C. § 134. We AFFIRM.

I. Statement of the Case

Claim 1 is illustrative of the subject matter on appeal and reads (App. Br. Claims App'x 2):

1. A composition having oxidative stability comprising:
polyunsaturated fatty acid or its salt or ester,
an antioxidative sesame component which is purified
from sesame or synthesized, and
ascorbic acid or an ascorbyl fatty acid ester.

In response to an election requirement, Appellants elected to prosecute sesamol as the antioxidative sesame component (Response to Election of Species Requirement filed May 22, 2007). Therefore, only compositions comprising sesamol as the antioxidative sesame component are before us.

The Examiner rejected claims 1 and 5-10 as unpatentable under 35 U.S.C. § 103(a) over Kataoka³ and/or Granata⁴ in view of Chavali I⁵ and/or

³ US Patent 6,235,331 B1, *Modified Fish Oil Type Material Containing Highly Unsaturated Fatty Acid and/or Esters Thereof and a Composition Containing Said Material*, issued 22 May 2001 to Kataoka et al. ("Kataoka").

⁴ International Patent Publication WO 02/058793 A1, *Essential N-3 Fatty Acids in Cardiac Insufficiency and Heart Failure Therapy*, published 1 August 2002, Granata et al. ("Granata").

⁵ Chavali et al., *Composition Useful for Treating a Disorder Such as Adult Respiratory Distress Syndrome in a Mammal Comprises Sesamol or Its Metabolite*, Derwent World Patent Index Accession No. 2002-040630 (2002) ("Chavali I").

II,⁶ Maguire,⁷ Chen I⁸ and/or II,⁹ and Wechter¹⁰ (Ans. 3-6; Communication 1). The Examiner found that both Kataoka and Granata teach treating cardiovascular disease with polyunsaturated fatty acids or esters, e.g., eicosapentaenoic acid ethyl ester ("EPA") or docosahexaenoic acid ("DHA") (*id.* at. 4). The Examiner found that Chavali, Maguire, Chen, and Wechter teach treating cardiovascular disorders with sesamol, ascorbyl palmitate, ascorbic acid, and tocopherol, respectively (*id.* at 4-5). The Examiner concluded that it would have been obvious to one of ordinary skill in the art to combine sesamol, ascorbyl palmitate, ascorbic acid, and tocopherol with the polyunsaturated fatty acid esters of Kataoka and/or Granata to form a composition for treating cardiovascular disorders in view of Chavali's, Maguire's, Chen's, and Wechter's teachings that these ingredients are useful for the same purpose (*id.* at 5).

⁶ US Patent Application Publication 2001/0031275 A1, *Sesamol Inhibitors of Delta-5-Desaturase Activity and Uses Thereof*, published 18 October 2001, Forse et al. ("Chavali II").

⁷ Maguire et al., *Preparation of Edible Water-in-Oil Emulsions Containing Fish Oil and Ascorbyl Palmitate*, Derwent World Patent Index Accession No. 1995-054394 (1995) ("Maguire").

⁸ Chen et al., *New Phytosterol and/or Phytostanol and Ascorbic Acid Containing Derivatives Useful in Treating, e.g., Cardiovascular Disease*, Derwent World Patent Index Accession No. 2003-219905 (2003) ("Chen I").

⁹ US Patent Application Publication 2002/0156051 A1, *Novel Structures Comprising Phytosterol and/or Phytostanol and Ascorbic Acid and Use Thereof in Treating Cardiovascular Disease, Its Underlying Conditions and Other Disorders*, published 24 October 2002, Kutney et al. ("Chen II").

¹⁰ US Patent 6,242,479 B1, *Use of γ -Tocopherol and Its Oxidative Metabolite LLU- α in the Treatment of Disease*, issued 5 June 2001 to William J. Wechter ("Wechter").

The Examiner also relied on Tallarida¹¹ as rebuttal evidence.

Appellants argue that sesamol and ascorbic acid/ascorbyl fatty acid esters are added to the composition of Kataoka or Granata for a different purpose, i.e., to form a third composition with dramatically improved oxidative stability (App. Br. 5). Appellants further argue that the synergistic effect shown by the examples in the Specification, and illustrated in Figures 1, 5, 10-12, and 14, are effective to rebut any *prima facie* case of obviousness (*id.* at 6-8; Reply Br. 4-6).

Appellants have not separately argued the patentability of dependent claims 5-20 (App. Br. 9). Therefore, we decide this appeal on the basis of claim 1. 37 C.F.R. § 41.37(c)(1)(vii). At issue is whether it would have been *prima facie* obvious to combine a polyunsaturated fatty acid or its salt or ester with sesamol and ascorbic acid or an ascorbyl fatty acid ester to form a composition based upon the combined disclosures of the applied prior art; and, if so, whether Appellants have provided evidence that, when weighed with the evidence of obviousness, is sufficient to overcome the *prima facie* conclusion of obviousness.

II. Findings of Fact

The following findings of fact ("FF") are supported by a preponderance of the evidence of record.

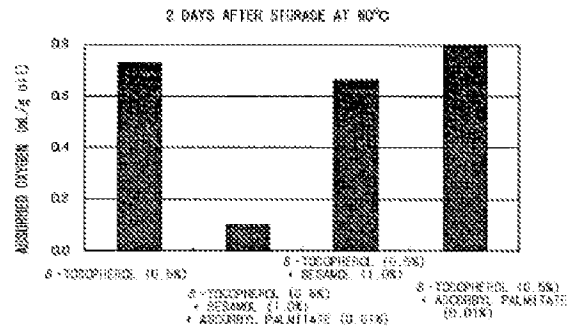
- [1] Kataoka teaches that highly unsaturated fatty acids and esters thereof, such as EPA, contained in fish oil are known to be effective in the prevention and treatment of cardiac infarction and arteriosclerosis (Kataoka 1:23-30).

¹¹ R. Tallarida, DRUG SYNERGISM AND DOSE-EFFECT DATA ANALYSIS, Chapman & Hall/CRC publishers, Boca Raton (2000), pp. 8-10 ("Tallarida").

- [2] Granata teaches using a composition containing a mixture of EPA and DHA for the prevention and treatment of heart disease, specifically, cardiac insufficiency and/or heart failure (Granata abstract; 3:19-23).
- [3] Chavali teaches that a composition comprising sesamol is useful for treating disorders including cardiovascular disease (Chavali I 1-2; Chavali II ¶ 35, claim 29).
- [4] Maguire teaches preparing an edible water-in-oil emulsion comprising fish oil containing ascorbyl palmitate for protection against heart disease (Maguire 1-2).
- [5] Chen teaches chemical structures comprising (a) phytosterol or phytostanol and (b) ascorbic acid useful in the treatment or prevention of cardiovascular disease (Chen I, 1-2; Chen II 3, ¶¶ 12-15).
- [6] Wechter teaches using γ -tocopherol and derivatives thereof to treat and prevent cardiovascular disease (Wechter abstract; 2:27-34).
- [7] Figure 1 of the 413 Application illustrates the amount of oxygen absorbed by samples of (a) refined fish oil containing 0.5 %¹² δ -tocopherol ("refined fish oil"), (b) refined fish oil plus 1.0% sesamol and 0.01% ascorbyl palmitate, (c) refined fish oil plus 1.0% sesamol, and (d) refined fish oil plus 0.01% ascorbyl palmitate after storage at 60°C for two days (Spec. 25:1-22). Figure 1 is reproduced below.

¹² Percentages are given as weight %.

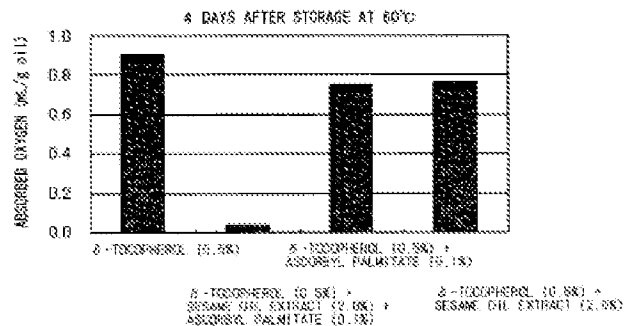
Fig. 3



{Figure 1 of the 413 Application shows the amounts of oxygen absorbed by oil in Example 1.}

- [8] Figure 5 of the 413 Application illustrates the amount of oxygen absorbed by samples of (a) refined fish oil, (b) refined fish oil plus 2.0% sesame oil extract and 0.1 % ascorbyl palmitate, (c) refined fish oil plus 0.1% ascorbyl palmitate, and (d) refined fish oil plus 2.0% sesame oil extract after storage at 60°C for 4 days (Spec. 27:16-28:16). Figure 5 is reproduced below.

Fig. 5



{Figure 5 of the 413 Application shows the amounts of oxygen absorbed by oil in Example 5.}

- [9] In Example 11 of the 413 Application, preparations of (i) 0.5% sesamol and 0.1% ascorbyl palmitate or (ii) 1.0% sesamol and 0.1% ascorbyl palmitate were added to refined fish oil to provide test samples that were sealed and stored at 60°C. The concentration of oxygen in the samples as well as the concentrations of sesamol,

ascorbyl palmitate, and δ -tocopherol were measured over time (Spec. 33:21-34:17.) Figures 10 and 11 show the results from samples made with preparations (i) and (ii), respectively, and are reproduced below.

FIG. 10

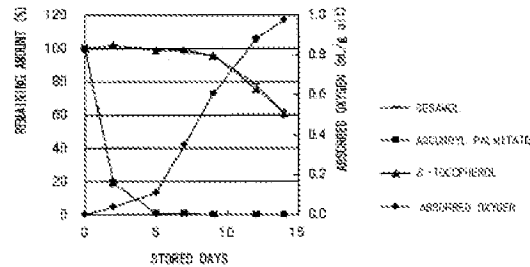
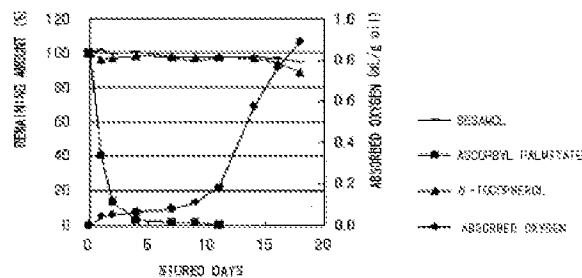


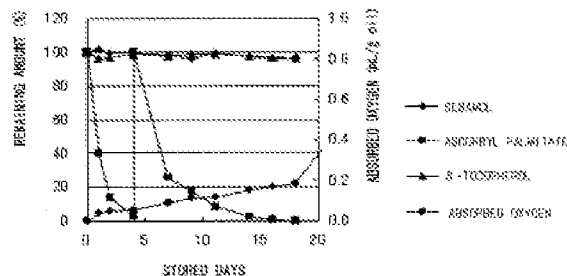
Fig. 11



{Figures 10 and 11 of the 413 Application shows changes in the amount of oxygen absorbed by sample over time, and the remaining amounts of antioxidants.}

- [10] Figure 12 of 413 Application shows the effect of adding 0.1% ascorbyl palmitate to the same system as in Figure 11 on day four. Figure 12 is reproduced below.

FIG. 12



{Figure 12 of the 413 Application shows the effect of adding ascorbyl palmitate to the system of Figure 11 on day 4.}

III. Discussion

A. Legal principles

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and, (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Indeed, "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). Also, it is well settled that it is not necessary for a finding of obviousness that all the advantages of a claimed invention are recognized by the prior art, and it is not necessary for such finding that the motivation of one of ordinary skill in the art be the same as the applicant's motivation. *See In re Kemps*, 97 F.3d 1427, 1430 (Fed. Cir. 1996); *In re Dillon*, 919 F.2d 688, 693 (Fed. Cir. 1990).

The burden of demonstrating unexpected results rests on the party asserting them, and "it is not enough to show that results are obtained which differ from those obtained in the prior art: that difference must be shown to be an *unexpected* difference." *In re Klosak*, 455 F.2d 1077, 1080 (CCPA 1972). Moreover, a showing of unexpected results must be commensurate in scope with the breadth of the claims. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983).

B. Analysis

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose."

Kerkhoven, 626 F.2d at 850. Therefore, we agree with the Examiner that it would have been *prima facie* obvious to combine sesamol and ascorbyl palmitate/ascorbic acid with a polyunsaturated fatty acid/ester to obtain a composition useful for treating cardiovascular disorders since all three of these agents are taught or suggested to be useful for treating cardiovascular disorders by Katakoka (FF1 (polyunsaturated fatty acid/ester)), Granata (FF 2 (polyunsaturated fatty acid/ester)), Chavali (FF 3 (sesamol)), Maguire (FF 4 (ascorbyl palmitate)), and Chen (FF 5 (ascorbic acid)). It is not necessary that the motivation of one of ordinary skill in the art to make the combination be the same as Appellants' motivation. *Dillon*, 919 F.2d at 693. Nor is it necessary that all of the advantages of the claimed composition, e.g., improved stability, are recognized by the prior art. *Kemps*, 97 F.3d at 1430. The question then becomes whether Appellants have provided evidence sufficient to overcome the *prima facie* conclusion of obviousness in this case. We think not.

A showing of unexpected results must be commensurate in scope with the breadth of the claims. *Grasselli*, 713 F.2d at 743. Here, Appellants argue that the claimed composition has dramatically improved oxidative stability. However, claim 1 does not require any particular improvement in stability, e.g., in terms of degree, duration, storage conditions, etc. Similarly, the composition of claim 1 is not limited to any particular concentration, ratio, etc. of its components. For example, claim 1 encompasses the

compositions existing at day 4 in Figures 10-12 of the 413 Application (*see* FF 9-10). Therefore, we agree with the Examiner that Appellants' showing of unexpected results is not commensurate in scope with the claimed invention.

Furthermore, it is not enough show that the results are different when sesamol and ascorbyl palmitate are used together, as opposed to separately. Appellants must show that the results are *unexpectedly* different. *Klosak*, 455 F.2d at 1080. Here, Appellants have merely demonstrated a difference and, therefore, have not met their burden of persuasion. In this regard, we note that Appellants' own Background Section states that "[i]n order to enhance the oxidative stability of oils and fats, various types of antioxidants have been used ... in combination, or a synergist, such as ... ascorbic acid, is added to the antioxidant to enhance the antioxidant properties" (Spec. 3:24-4:4).

C. Conclusion

We sustain the rejection of claims 1 and 5-20 under § 103 over Kataoka and/or Granata in view of Chavali I and/or II, Maguire, Chen I and/or II, and Wechter. It would have been *prima facie* obvious to combine a polyunsaturated fatty acid or its salt or ester with sesamol and ascorbic acid or an ascorbyl fatty acid ester to form a composition based upon the combined disclosures of the applied prior art; and, Appellants have not provided evidence that, when weighed with the evidence of obviousness, is sufficient to overcome the *prima facie* conclusion of obviousness.

IV. Order

Upon consideration of the record, and for the reasons given, it is

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ORDERED that the decision of the Examiner to reject claims 1 and 5-20 as unpatentable under 35 U.S.C. § 103(a) over Kataoka and/or Granata in view of Chavali I/II, Maguire, Chen I/II, and Wechter is AFFIRMED; and,

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R.

§ 1.136(a)(1)(iv).

AFFIRMED

cdc

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